PATENT COOPERATION TREATY

RCD 09 SEP 2005

WIPO PCT

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 2003019-WO	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/DK2004/000427	International filing date *(day/month/year)* 18.06.2004	Priority date *(day/month/year)* 19.06.2003
International Patent Classification (IPC) or national classification and IPC A61L15/44, A61L26/00		
Applicant COLOPLAST A/S		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 7 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES; comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 4 sheets, as follows:
      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☒	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
18.04.2005	13.09.2005
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Thornton, S Telephone No. +31 70 340-4182

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/DK2004/000427

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages	
1-22	as originally filed
Claims, Numbers	
1-29	received on 20.04.2005 with letter of 19.04.2005
Drawings, Sheets	
1/4-4/4	as originally filed

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/DK2004/000427

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 29(partly)

because:

☒ the said international application, or the said claims Nos. 29(partly) relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos.

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form
- ☐ has not been furnished
- ☐ does not comply with the standard

the computer readable form
- ☐ has not been furnished
- ☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/DK2004/000427

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-29
	No:	Claims	
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-29
Industrial applicability (IA)	Yes:	Claims	1-28
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

and / or

2. Non-written disclosures (Rule 70.9)

see separate sheet

Re Item III.

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy - claim 29.

Re Item V.

1 The following documents are referred to in this communication:

D1 : WO 00/02539 A
D2 : WO 01/80797 A
D3 : WO 98/22114 A
D4 : US 5 719 197 A
D5 : GB 2 311 027 A
D6 : US 5 792 469 A
D7 : US 5 993 849 A

2 INDEPENDENT CLAIM 1

2.1 Document D1 discloses a topical plaster containing anti-inflammatory drugs (see D1, claims).

2.2 Document D2 discloses a medicated wrap containing drugs, e.g. Rofecoxib, Celecoxib, etc. (see D2, page 10, line 12-35; page 11, line 1-3).

2.3 Document D3 discloses a method for promoting tissue repair using various drugs (see D3, page 29, line 29-32; page 30,31). The composition is incorporated into a cream or ointment, or is in the form of a powder. The reference is silent with respect to incorporation into a dressing.

2.4 Document D4 discloses a composition for topical administration of pharmaceutical agents (see D4, column 21, line 51-67; column 22, line 1-18).

2.5 Document D5 discloses coated absorbable beads for wound treatment comprising, e.g. Ibuprofen, Naproxen, Acetaminophen, etc. (see D5, page 4, line 11-12). The reference is silent with respect to how it may be used as a wound dressing.

2.6 Document D6 discloses a biodegradable in situ film forming liquid dressing comprising various drugs (see D6, column 9, line 41-44). The composition is applied and not removed again but is left to degrade.

2.7 Document D7 discloses a hydrophilic adhesive and binder for medications (see D7, claims).

2.8 D1, D2 and D7 disclose medical dressings or wraps with incorporated painkillers. D4 discloses a composition for topical delivery. However, all 3 references are for transdermal use, and the references are silent with respect to use on open wounds.

2.9 Therefore, the subject-matter of independent claims 1,29 is novel in the sense of Article 33(2) PCT.

3 INVENTIVE STEP

3.1 The **problem** to be solved can be regarded as to provide a wound care device that supplies pain relief locally to a wound and nearby surroundings but not systemically, i.e. in the body, to reduce or eliminate side effects and capable of releasing a pain-killing agent to a wound even when only low levels of exudates are present.

3.2 The **solution** disclosed in claim 1 is a wound care device comprising an active pain killing agent, said device being capable of releasing a painkilling agent to a wound even when only low levels of exudates are present, that supplies pain relief locally to a wound and nearby surroundings and wherein at least 50% w/w of the pain-killing agent is released during the first 24 hours after application and wherein a majority of said pain killing agent is in direct contact with the wound.

3.3 Claim 1 therefore lists desiderata without detailing how such effects can be achieved.

3.4 There is not sufficient technical disclosure of the composition of the wound dressing for a person skilled in the art to provide a wound dressing device from the content of claim 1 to solve the problem posed.

3.5 Indeed, it would be obvious to a person skilled in the art to provide a wound care device that supplies pain relief locally to a wound and nearby surroundings but not systemically, i.e. in the body, to reduce or eliminate side effects - hence claim 29 does not involve an inventive step in the sense of Article 33(3) PCT.

3.6 At present, therefore, the provision of a wound care device that comprises a low-level of a pain-killing agent as disclosed in the subject-matter of claim 1 does not involve an inventive step in the sense of Article 33(3) PCT.

4 DEPENDENT CLAIMS 2-28

Dependent claims 2-28 being dependent on claim 1, meet the requirements of the PCT in respect of novelty and inventive step [Article 33(2) and (3) PCT].

CLAIMS

1. A wound care device comprising an active pain killing agent, said device being capable of releasing a painkilling agent to a wound even when only low levels of exudates are present, that supplies pain relief locally to a wound and nearby surroundings and wherein at least 50% w/w of the pain-killing agent is released during the first 24 hours after application and wherein a majority of said pain killing agent is in direct contact with the wound.

2. A wound care device according to claim 1 wherein the amount of pain killing agent in the device is below the lowest daily unit dose for systemic treatment.

3. A device according to any of the preceding claims, wherein the pain-killing agent is an anti-inflammatory pain-killing agent.

4. A device according to any of the preceding claims, wherein the device has a maximum absorption of 0,2 g/cm^2.

5. A device according to any of the preceding claims, wherein the device is substantially non-absorbent.

6. A device according to any of the preceding claims, wherein the release of the pain-killing agent is substantially independent of the amount of wound exudate.

7. A wound care device according to any of the preceding claims wherein the pain killing agent is released to the wound in such a way that substantially no effective systemic plasma concentration of the pain killing agent can be found.

8. A device according to any of the preceding claims, wherein at least 50% w/w of the pain-killing agent is released during the first 12 hours after application.

9. A device according to any of the preceding claims, wherein at least 50% w/w of the pain-killing agent is released during the first 6 hours after application.

10. A device according to any of the preceding claims, wherein at least 75% w/w of the pain-killing agent is released during the first 24 hours after application.

11. A device according to any of the preceding claims, wherein at least 75% w/w of the pain-killing agent is released during the first 12 hours after application.

12. A device according to any of the preceding claims, wherein at least 75% w/w of the pain-killing agent is released during the first 6 hours after application.

13. A device according to any of the preceding claims, wherein at least 90% w/w of the pain-killing agent is released during the first 24 hours after application.

14. A device according to any of the preceding claims, wherein at least 90% w/w of the pain-killing agent is released during the first 12 hours after application.

15. A device according to any of the preceding claims, wherein at least 90% w/w of the pain-killing agent is released during the first 6 hours after application.

16. A device according to any of the preceding claims, wherein the device comprises one or more components selected from the group of PVP, PVA, polylactic acids, polysaccharides such as carboxy methyl cellulose, hydroxymethyl cellulose, chitosan, alginate, or polyacrylic acids, methacrylates, silicones, styrene-isoprene-styrene mixtures, vaseline, glycols such as PEG or PEG/PPG mixtures or polyurethane.

17. A device according to any of the preceding claims, wherein the amount of pain killing agent is less than 75% of the daily unit dose for systemic treatment using the agent.

18. A device according to any of the preceding claims, wherein the amount of pain killing agent is less than 50% of the daily unit dose for systemic treatment using the agent.

19. A device according to any of the preceding claims, wherein the pain-killing agent is a NSAID.

20. A device according to any of the preceding claims, wherein the pain-killing agent is ibuprofen.

21. A wound care device according to any of the preceding claims wherein the pain killing agent is provided on the wound facing surface of the device.

22. A wound care device according to any of claims 1-20 wherein the pain killing agent is provided in a relatively thin wound-contacting layer.

23. A wound care device according to any of the preceding claims wherein the device has a thickness of less than1,5 mm.

24. A wound care device according to any of the preceding claims wherein the device exhibits non-stick properties with regards to the wound.

25. A wound care device according to any of the preceding claims wherein the device is in the form of a sheet-like layer.

26. A wound care device according to claim 25 wherein the layer is prepared from a web, a net, a knit, a woven or a non-woven fabric, a permeable or perforated film or a foam or a hydrogel.

27. A wound care device according to any of the preceding claims wherein the device is in the form of an open fabric being coated or impregnated with a composition comprising the pain-killing agent.

28. A wound care device according to claim 27 wherein the composition further comprises a non-stick agent.

29. A method of treating pain at a wound site comprising applying to the wound a wound care device comprising an active pain relieving composition, said compo-

sition is an anti-inflammatory pain killing agent, wherein the amount of pain killing agent in the device is below the daily unit dose for systemic treatment and wherein a majority of the pain killing agent is brought into direct contact with the wound.

5